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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,038	07/11/2003	Peter Andersen	SSISAUSA	5215
270 7590 12/08/2008 HOWSON AND HOWSON SUITE 210 501 OFFICE CENTER DRIVE FT WASHINGTON, PA 19034			EXAMINER SWARTZ, RODNEY P	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 12/08/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/617,038

Applicant(s)

ANDERSEN ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-10, 12, 13, 16, 17 and 24-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-10, 12, 13, 16, 17 and 24-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' Response to Office Action, received 27 August 2008, is acknowledged. New claims 28 and 29 have been added.
2. Claims 6-10, 12, 13, 16, 17 and 24-29 are pending and under consideration.

Rejections Withdrawn

3. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Horwitz (U.S. Pat. No. 5,108,745), is moot in light of the cancellation of the claim.

Rejections Maintained

4. The rejection of claims 12 and 13 under 35 U.S.C. 102(b) as being anticipated by Horwitz (U.S. Pat. No. 5,108,745), is maintained for reasons of record.

Applicants argue that there is no written description or enabling support for the claims of the patent, does not teach or suggest *M. tuberculosis* antigens which are upregulated or expressed during the latent stage of a tuberculosis, and does not teach or suggest specific Mycobacterium antigens.

The examiner has considered applicants' arguments, but does not find them persuasive. Horwitz teaches a therapeutic vaccine against *M. tuberculosis* comprising ≥ 1 extracellular product of *M. tuberculosis* and a pharmaceutically acceptable adjuvant (claims 13-17; col. 4, lines 23-26). In the absence of evidence to the contrary, the extracellular products of *M. tuberculosis* contain the required ≥ 1 polypeptide or fragments thereof (such as CFP10) which are upregulated or expressed during the latent state of the mycobacteria infection. Applicants have provided no evidence that the extracellular products taught by Horwitz do not contain the required polypeptide or fragments thereof.

5. The rejection of claims 6-10, 12, 13, 16, 17, and 24-27 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained for reasons of record.

Applicants argue that it is common knowledge that immunogenic properties of a peptide can be maintained with changes of the amino acid sequence, that the mechanism of an antigen used in a vaccine is due to specific epitopes within this antigen that are immunogenic, and it is easy for a person skilled in the art to find these fragments and analogues.

The examiner has considered applicants' arguments, but does not find them persuasive for the reasoning put forth in the original rejection. Applicants' arguments are directed to enablement issues, i.e., could one possibly find such vaccines comprising said fragments given the teachings of the specification. This is not the basis of the instant rejection. The rejection is that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention of vaccines comprising fragments of SEQ ID NOs:1-23, 25-45, or vaccines comprising sequences $\geq 70\%$ identity to SEQ ID NOs:1-45. There is insufficient evidence that the written description requirement was fulfilled.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Newly added claims 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Horwitz (U.S. Pat. No. 5,108,745).

One embodiment of newly added claim 28 is a therapeutic vaccine against tuberculosis comprising ≥ 1 polypeptide and a pharmaceutically acceptable adjuvant, which polypeptides are upregulated or expressed during the latent state of the mycobacteria infection.

Horwitz teaches a therapeutic vaccine against *M. tuberculosis* comprising ≥ 1 extracellular product of *M. tuberculosis* and a pharmaceutically acceptable adjuvant (claims 13-17; col. 4, lines 23-26). In the absence of evidence to the contrary, the extracellular products of *M. tuberculosis* contain the required ≥ 1 polypeptide (such as CFP10) which are upregulated or expressed during the latent state of the mycobacteria infection.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Newly added claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to the vaccine according to claim 1. Claim 1 has been canceled. Thus, it is unclear what vaccine composition is being referred to in claim 29.

Conclusion

10. No claims are allowed.
11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of

the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

November 24, 2008

Application Number**Application/Control No.**

10/617,038

**Applicant(s)/Patent under
Reexamination**

ANDERSEN ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645